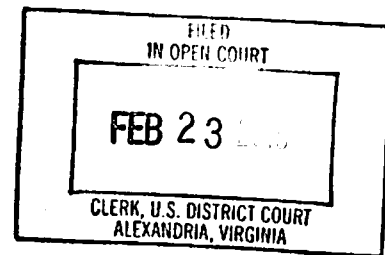


UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division



UNITED STATES OF AMERICA

v.

REUVEN MIRLIS,

Defendant

Criminal No. 1:14-cr-397-7

Hon. Anthony J. Trenga

STATEMENT OF FACTS

The United States and the defendant, REUVEN MIRLIS, agree that the following facts are true and correct, and that had this matter proceeded to trial, the United States would have proven them beyond a reasonable doubt with admissible and credible evidence:

1. Beginning in at least April 2011, and continuing until December 2014, in the Eastern District of Virginia and elsewhere, defendant REUVEN MIRLIS, together with co-conspirators including TC MEDICAL GROUP, SB MEDICAL INC., DAVID E. BURKE, a/k/a "David Johnson," TZVI LEXIER, HANOCH DAVID STEIN, a/k/a "Albert Simmins," and ASAF AKIVA IBRAHIMIAN, a/k/a "Adam Darius," and other individuals including co-conspirators based in Canada, including R.L. and S.R., co-conspirators in Germany, including C.G., and co-conspirators in the United States, including A.T. in Baltimore, Maryland; R.R. and M.R. in Lakewood, New Jersey; S.M. and E.M. in Edison, New Jersey; and A.B. in Boynton Beach, Florida, and with intent to defraud and mislead, engaged in a conspiracy to smuggle into and distribute within the United States, including within the Eastern District of Virginia, misbranded prescription drugs and devices.

2. Specifically, members of the conspiracy did knowingly and intentionally combine, conspire, confederate, and agree, with each other and with other persons, to: (a)

defraud the United States and its agencies by: impeding, impairing, and defeating the lawful functions of the Food and Drug Administration (“FDA”) to protect the health and safety of the public by ensuring that prescription drugs and devices distributed in the United States were safe and effective from the time of manufacturing to the delivery to the entity that sold or dispensed the product to the ultimate consumer or patient; and impeding, impairing, and defeating the lawful functions of Customs and Border Protection (“CBP”) and Immigration and Customs Enforcement—Homeland Security Investigations (“ICE-HSI”) to protect the public health and safety by governing the importation into the United States of goods and merchandise, including drugs and devices, through deceitful and dishonest means; (b) fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law; (c) introduce into interstate commerce misbranded prescription drugs and devices; and (d) knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the United States, including to the Commonwealth of Virginia without being licensed to do so.

3. The misbranded and non-FDA approved prescription drugs and devices smuggled and sold by members of the conspiracy included orthopedic injections, rheumatology infusions, cosmetic devices, optomology products, and oncology drugs, which were often subject to stringent storage and handling requirements (such as cold-chain products required to be kept at a consistently low temperature for their safe use), and FDA “black box warnings” which is the strongest warning the FDA requires. The FDA requires “black box warnings” when a drug carries a significant risk of serious or life-threatening adverse effects.

4. The prescription drugs and devices smuggled and distributed by members of the conspiracy were misbranded because they failed to bear adequate directions for use in that they, among other things, (a) were not in the possession of a person, or his agents or employees, who was regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices; (b) failed to bear a label that contained the required language limiting their use to prescription only and for prescription drugs; (c) failed to bear the FDA-approved labeling and/or at any time before dispensing its label failed to bear, at a minimum, the “Rx only” symbol. The drugs and devices were also misbranded in some cases because the required labeling failed to bear information required under the FDCA in the English language. 21 U.S.C. § 352(f)(1).

5. In addition, neither defendant REUVEN MIRLIS nor any of his co-defendants and co-conspirators were licensed wholesale distributors permitted to sell prescription drugs within the United States and in the Commonwealth of Virginia, and so were not regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States. Neither MIRLIS nor any of his co-defendants and co-conspirators adhered to appropriate storage and handling, record-keeping, and reporting requirements as would be required of lawful and licensed wholesalers in the United States. In particular:

a. Facilities used by members of the conspiracy for the storage and handling of prescription drugs and devices consisted of unregistered commercial mailboxes at United Parcel Service (“UPS”) and other commercial vendors, residential backyards and porches, basement rooms, garages, kitchen fridges and freezers, and personal residences which did not have adequate lighting, ventilation, temperature, humidity, and security as required for the safe handling and storage of prescription drugs and devices. Members of the conspiracy—who did not have any formal training or experience in handling prescription drugs and devices—did not

properly quarantine damaged, deteriorated, misbranded, or adulterated prescription drugs and in some cases caused them to be shipped to United States doctors and medical practices.

b. Shipping methods used by members of the conspiracy were designed to evade law enforcement detection, and so often took weeks to arrive in the United States from abroad. Instead of using dry ice or other means of appropriately packing prescription drugs and devices and shipping them by overnight mail, members of the conspiracy often used ice packs and cooling packs, Styrofoam boxes, and other picnic cold packs from Walmart or other stores for shipment over longer periods of time, and often failed to keep cold chain prescription drugs at the required temperatures altogether. As a result, certain FDA-regulated products required to be kept at low and specific temperatures routinely arrived warm, wet, or otherwise damaged.

c. Members of the conspiracy, not being regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States, did not keep the required records and reports as required of lawful and licensed wholesalers in the United States.

6. TC MEDICAL GROUP and SB MEDICAL INC., under the leadership of DAVID E. BURKE and TZVI LEXIER, and others, caused misbranded and non-FDA approved prescription drugs and devices to be smuggled into the United States and distributed as follows:

a. Beginning in or around April 2011, members of the conspiracy purchased from co-conspiring foreign suppliers prescription drugs and devices manufactured and labeled for use in foreign countries, including the Republic of Turkey, Canada, France, Italy, the United Kingdom, and other countries, and caused them to be shipped into the United States. These prescription drugs and devices were forwarded to the United States through the United Kingdom to doctors and medical practices in the United States, or alternatively to locations including the

personal residences and mailboxes of co-conspiring individual drop shippers in the United States.

b. Drop shippers in the United States regularly received packages of prescription drugs and devices from abroad, removed labels and other indicia showing that they had been imported from abroad, repacked the orders, and re-shipped them to doctors and medical practices throughout the United States, including to the Eastern District of Virginia, to give the false impression that the drugs were being distributed domestically and legally.

c. To impede, impair, and defeat the lawful functions of the FDA, CBP, and ICE-HSI, the defendants, together with other co-conspirators, engaged in deceitful and dishonest means, including: (i) breaking up large shipments of prescription drugs and devices into smaller separate packages to be sent into the United States to multiple locations, under multiple names, over multiple days, to be consolidated upon arrival after evading border detection; (ii) shipping packages via Royal Mail and Parcelforce Worldwide, which—because they were United Kingdom-based services—allowed packages to be delivered through the United States Postal Service with less scrutiny than would be applied to packages arriving from other countries; (iii) including on customs forms misleading statements about the package contents and value, and addressing packages to co-conspirators under false names and/or titles; (iv) frequently mishandling prescription drugs subject to strict temperature requirements by failing to keep them at a consistent temperature during shipping and storage as required for the drug's safe and effective use; and (v) failing to keep and provide the appropriate pedigree records to prove or track the proper shipping, storage, and transaction history of prescription drugs through the supply chain.

7. Defendant REUVEN MIRLIS, together with co-defendant ASAF AKIVA IBRAHIMIAN were New Jersey-based sales representatives for TC MEDICAL GROUP and SB MEDICAL INC. responsible for selling misbranded prescription drugs and devices to customers in the United States, including doctors and medical practices in the Eastern District of Virginia. MIRLIS, who used the false name "Daniel Mirl," and IBRAHIMIAN, who used the false name "Adam Darius," co-owned R&A Consulting Group, a corporate entity, which received sales commissions from TC MEDICAL GROUP and SB MEDICAL INC. for the illegal sale of misbranded prescription drugs and devices.

8. Between approximately September 10, 2012 and approximately January 16, 2014, defendant REUVEN MIRLIS together with co-defendant ASAF AKIVA IBRAHIMIAN, through R & A Consulting, received approximately \$173,469.18 as commission payments for the sale of misbranded and non-FDA approved drugs and devices in the United States, including into the Eastern District of Virginia, for the TC MEDICAL GROUP and SB MEDICAL INC. organization. Those commissions represented approximately \$716,019.09 in gross revenue for TC MEDICAL GROUP and SB MEDICAL INC. From approximately April 2011 through December 3, 2014, TC MEDICAL GROUP and SB MEDICAL INC., under the leadership of TZVI LEXIER and DAVID E. BURKE, caused to be illegally imported and distributed misbranded prescription drugs and devices within the United States and the Eastern District of Virginia, misbranded and non-FDA approved prescription drugs and devices amounting to approximately \$18,494,285 in gross proceeds.

9. In addition, members of the conspiracy regularly communicated with each other via email about the foreign acquisition, illegal importation, sale of misbranded prescription drugs

and devices in the United States, and the transfer of proceeds from the United States back to Canada. For example:

a. On or about June 10, 2013, a co-conspirator emailed a drop shipper in the United States instructions later forwarded to defendant REUVEN MIRLIS:

my job is to make sure that myself and my co-workers have Enough Infusion medication in New Jersey... The shipping process works like this:

- 1- I arrange for product to be sent from the UK to you guys.
- 2- I will inform you in advance what the parcels are and when you should be expecting them.
- 3- I will provide you with tracking numbers, so that you will be aware of where the product is, when it should be arriving, and if any parcels are delayed in transit.
- 4- Once you receive the parcels/medication, you will keep the parcels packaged in the packaging they arrived in, and... Drive the Packages to [another United States-based drop shipper] Home, (Ideally the same day that you received them). Once you move... you will send the parcels on a FedEx overnight delivery service to one of the three addresses I will provide to you.

You will easily get used to scheduling FedEx pickups and printing shipping labels for the Parcels. Once FedEx picks up the medication they will automatically send you an email with the tracking numbers, which you will forward to me.

Please keep in mind that although what we and you are doing is technically completely legal, at the same time it is frowned upon. Therefore to avoid unnecessary attention to our company, you should never tell the FedEx delivery person that you are sending medication!!

Most of the time it will say cosmetics on the box, so as far as you know that is what you are shipping, and if they ask, that is what you will tell them...

b. On or about June 24, 2013, defendant ASAF AKIVA IBRAHIMIAN emailed a customer to explain that: "Our accounts receivable has moved to a new location" and provided the location of a house of a co-conspirator living in Lakewood, New Jersey. Defendant REUVEN MIRLIS, co-defendant ASAF AKIVA IBRAHIMIAN, and other co-conspirators, caused customers in the United States to mail payment checks to the personal residences and mailboxes of drop shippers in the United States to give the false impression that TC MEDICAL GROUP and SB MEDICAL INC. and their affiliates were based in the United States. Drop shippers in the United States did not cash the payment checks but instead forwarded the checks received to TC MEDICAL GROUP and SB MEDICAL INC. in Canada.

c. On or about July 12, 2013, co-defendant ASAF AKIVA IBRAHIMIAN emailed to a customer a letter purporting to be from the Chief Operation Office of TC MEDICAL GROUP signed by "Albert Simmons," the false name of co-defendant HANOCH DAVID STEIN. The letter claimed that: "The Orthovisc we purchase is being manufactured in an FDA approved facility... We have been distributing the Orthovisc for over eight years now..."

d. On or about July 22, 2013, a co-conspirator emailed defendant REUVEN MIRLIS and co-defendant ASAF AKIVA IBRAHIMIAN: "Orthovisc has just arrived at Yakub chemist. I'm sending 100 to Burke and 100 to Ross today. I'm not sending the 100 to Burke at the Brairwood address because we are sending 100 Synvisc Classic there today. It is too much to send in one day."

e. On or about September 9, 2013, defendant REUVEN MIRLIS emailed a co-conspirator to "lmk when there's an update on orthovisc for Europe." The co-conspirator responded: "The stock situation is going to be a nightmare buddy, be prepared to ship a lot from Europe direct... Impossible to tell when packages will arrive as some it takes 10 days, some it takes 16 days bro... That's the deal though, tzvi refuses to ship parcel force because it passed customs which is mad heat. With Royal Mail I guess it doesn't but takes so much longer."

f. On or about September 11, 2013, co-defendant ASAF AKIVA IBRAHIMIAN circulated a document labeled "Adam and Daniel's list of whats needed for their clinics.docx" listing United States customers and whether they accepted shipments of drugs and devices shipped directly from the United Kingdom or indirectly through a drop location in the United States.

g. On or about November 13, 2013, defendant REUVEN MIRLIS emailed co-defendant TZVI LEXIER: "I've worked hard to get in payments and over the last week and a half we have gotten between CC and checks over 60k"

h. On or about November 14, 2013, there was a transfer of \$18,375.34 from Scotia Bank account ending in 0915 held in the name of defendant SB MEDICAL INC. in Canada to Wells Fargo bank account ending in 2624 held in the name of R&A Consulting Group, the entity owned by defendant REUVEN MIRLIS and co-defendant ASAF AKIVA IBRAHIMIAN in New Jersey.

i. On or about November 26, 2013, a co-conspirator emailed defendant REUVEN MIRLIS and co-defendant ASAF AKIVA IBRAHIMIAN:

U want 125 Orthovisc fast? Well let me tell u a trick that might work but doesn't always. I would have 125 Orthovisc Parcel Forced to your client from Europe. Then tell the client, oopps, for some reason a wrong warehouse shipped you instead of our American branch. The client returns the 125 to NJ by UPS overnight. And u go ahead and ship the SAME 125 Orthovisc back to your client on an overnight basis. Tzvi and [a co-conspirator] refuse to Parcel Force anything EXCEPT the client themselves. This is probably the fastest way for you to get all 125 Orthovisc Fast to your client. Your other option is to wait and wait until there are enough and have to ship 3 times to the client until you fill the FULL order. This is crazy enough to just might work! :) ... AND you want to hear a more devious way of getting it there? Well, let's say your client DOESN'T ACCEPT stuff from Europe and it would be heat out to ship to them so.... Well, let's say you have a client who DOES accept Orthovisc from Europe so u send it to them, then apologize to them and say 'Accidently' the WRONG order was shipped to you I will have UPS pick this up from you...you with me so far???? Then u ship it via NJ to the REAL client on UPS. KABOOM!!@! Am I devious or am I devious mr. Darius?!?!?!

IBRAHIMIAN responded: "hahahahaha. i just read this whole thing. genius!"

j. On or about December 4, 2013, a co-conspirator emailed defendant REUVEN MIRLIS and co-defendant ASAF AKIVA IBRAHIMIAN: "We started removing the NJ warehouse addresses on the invoices to customers, it is heat I probably don't need to explain to you why we shouldn't have Moe R. address on every invoice going out to customers... Please remove all addresses from your invoices going forward. If your client is paying by check then u can call them and tell them orally or email once where they should send the checks but on the

invoice itself please remove it. As well, we have removed everyone's names off our website for obvious reasons."

k. On or about December 23, 2013, defendant REUVEN MIRLIS and co-defendant ASAF AKIVA IBRAHIMIAN received a message from a customer stating: "I just got off the phone again with Aetna pre auth dept and they will not authorize the orthovisc because the TC medical group does not have a tqax ID#. I called the tc medical group and they said since they were a company based outside the US they do not have a tax ID#???"

l. On or about March 6, 2014, co-defendant ASAF AKIVA IBRAHIMIAN forwarded an email from a customer asking how much Orthovisc was in stock. The email was addressed to "Adam Darius," the false name of IBRAHIMIAN. IBRAHIMIAN forwarding the email stated: "of course this isnt ADAM:)"

10. The statement of facts includes those facts necessary to support the defendant's guilty plea. It does not include each and every fact known to the defendant or to the government and it is not intended to be a full enumeration of all of the facts surrounding the defendant's case.

11. The actions of the defendant, as recounted above, were in all respects knowing, voluntary, and intentional, and were not committed by mistake, accident or other innocent reason.

12. The defendant waives any rights under Fed. R. Crim. P. 11(f), Fed. R. Evid. 410, the United States Constitution, and any federal statute or rule in objecting to the admissibility of the Statement of Facts in any such proceeding.

Dana J. Boente
United States Attorney


By:



Alexander T.H. Nguyen
Jay V. Prabhu
Assistant United States Attorneys

Defendant's Signature: After consulting with my attorney, I hereby stipulate that the above Statement of Facts is true and accurate and that had the matter proceeded to trial, the United States would have proved the same beyond a reasonable doubt.


Date: 2/12, 2015



Reuven Mirlis
Defendant

Defense Counsel Signature: I am Reuven Mirlis's attorney. I have carefully reviewed the above Statement of Facts with him. To my knowledge, his decision to stipulate to these facts is an informed and voluntary one.

Date: 2/12, 2015



Peter David Greenspun, Esq.
Counsel for the Defendant